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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,899	11/19/2001	Hendricus Renerus Jacobus Mattheus Hoogenboom	DX/003 CON	9170

1473 7590 04/06/2004  
FISH & NEAVE  
1251 AVENUE OF THE AMERICAS  
50TH FLOOR  
NEW YORK, NY 10020-1105

EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/988,899

### Applicant(s)

HOOGENBOOM, HENDRICUS  
RENERUS JACOBUS M

### Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/25/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The response filed on 1/9/04 has been fully considered and entered into the application.
2. Applicant's election without traverse of group I, claims 1-3 and 10 in Paper filed on 1/9/04 is acknowledged.
3. Claims 4-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on 1/9/04.
4. Claims 1-3 and 10 are currently being examined in this application.

### ***Priority***

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on 5/18/99. It is noted, however, that applicant has not filed a certified copy of the European Patent application as required by 35 U.S.C. 119(b).
6. Applicants are requested to include priority application data in the specification page 1, line 1.

### ***Information Disclosure Statement***

7. The information disclosure statement filed on 5/25/02 has been fully considered and entered into the application.

### ***Claim Objections***

8. Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 10 depends on a multiple dependent claim 3. See MPEP § 608.01(n). Accordingly, the claim 10 has not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the vector" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites 'polynucleotide according to claim 1', however the claim 1 does not recite '**polynucleotide**'. If applicants mean that 'the plurality of polynucleotides of claim 1', applicants are requested to amend the claim.

Claim 3 is indefinite by reciting 'preferably' and 'most preferably', applicants are requested to site exact number of Fabs.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/05781 (reference provided by applicants in PTO 1449 filed on 5/25/02).

The instant claims briefly recite a library of vectors comprising, a) first and second cloning region comprising unique restriction enzyme cleavage site, a ribosome binding site and a signal sequence, b) a polynucleotide encoding anchor region, c) a first and second variable antibody regions.

WO 94/05781 teaches filamentous phage comprising heterologous polypeptides fused to filamentous phage coat protein membrane anchor and a heterodimeric receptor comprised of first and second receptor polypeptides (refers to the refers to antibody variable regions of the instant claims). The reference teaches library of phage particles containing plurality of phage particles containing heterologous fusion polypeptides on its surface (e.g., see page 28). The reference teaches preferably the library comprised of phage containing DNA that encodes at least  $10^6$ , preferably  $10^7$  and more preferably  $10^{8-9}$  different heterodimeric receptors of the invention (refers to instant claim 3) (e.g., se page 28). The reference teaches vectors comprising first and second cloning regions comprising restriction enzyme cleavage sites (e.g., figure 5), each cloning region has at the 5' end a ribosome binding site (RIBISI) (e.g., see figure 5), a first and second antibody variable regions (heavy chain fragment and light chain fragment in figure 5) (refers to instant claim 2). Thus, the reference clearly anticipates the claimed invention.

13. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 844306 A1 (reference provided by applicants in PTO 1449 filed on 5/25/02) .

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The instant claims briefly recite a library of vectors comprising, a) first and second cloning region comprising unique restriction enzyme cleavage site, a ribosome binding site and a signal sequence, b) a polynucleotide encoding anchor region, c) a first and second variable antibody regions.

EP 844306 A1 teaches methods for producing members of specific binding pairs. The reference teaches DNA encoding a genetically diverse population of specific binding pairs in recombinant host cells. The reference teaches that the recombinant genetic packages (refers to the vectors of the instant claims). The reference teaches a library of  $10^{14}$  possible clones expressing the combination of H and L chain (refers to instant claim 3) (e.g., see page 6). The reference vector comprises rbs at the 5' end of cloning regions, restriction enzyme sites and first and second cloning regions comprising Vh and Vl antibody fragments, gIII at the 3' end of the second cloning region (e.g., see figure 27). The reference clearly anticipates the claimed invention.

14. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,969,108 (note the instant application does not get the priority date of the EP application.).

The instant claims briefly recite a library of vectors comprising, a) first and second cloning region comprising unique restriction enzyme cleavage site, a ribosome binding site and a signal sequence, b) a polynucleotide encoding anchor region, c) a first and second variable antibody regions.

US Patent 5,969,108 teaches methods for producing members of specific binding pairs. The reference teaches DNA encoding a genetically diverse population of specific binding pairs

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in recombinant host cells. The reference teaches that the recombinant genetic packages (refers to the vectors of the instant claims). The reference teaches a library of  $10^{14}$  possible clones expressing the combination of H and L chain (refers to instant claim 3) (e.g., see column 6). The reference teaches vectors (or genetic packages) comprising from 5' to 3', rbs-enzyme cleavage site, vH –rbs-enzyme cleavage site-vL-N' terminus of gene III (e.g., see figure 45). Thus the reference clearly anticipates the claimed invention.

15. Claims 1-3 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,172,197 B1.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The instant claims briefly recite a library of vectors comprising, a) first and second cloning region comprising unique restriction enzyme cleavage site, a ribosome binding site and a signal sequence, b) a polynucleotide encoding anchor region, c) a first and second variable antibody regions.

US Patent 6,172,197 B1 teaches methods for producing members of specific binding pairs. The reference teaches DNA encoding a genetically diverse population of specific binding pairs in recombinant host cells. The reference teaches that the recombinant genetic packages

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(refers to the vectors of the instant claims). The reference teaches a library of  $10^{14}$  possible clones expressing the combination of H and L chain (refers to instant claim 3) (e.g., see column 6). The reference teaches vectors (or genetic packages) comprising from 5' to 3', rbs-enzyme cleavage site, vH –rbs-enzyme cleavage site-vL-N' terminus of gene III (e.g., see figure 45). Thus the reference clearly anticipates the claimed invention.

### *Conclusion*

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri  
Primary Examiner  
Art Unit 1639

Pp  
02 April 2004

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**